ASSESSMENT OF SSG (SALINE SONOSALPINGOGRAPHY) IN ASSESSING TUBAL PATENCY BY COMPARISON WITH CHROMOPERTUBATION IN LAPAROSCOPY

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ABSTRACT

BACKGROUND

Objective- To evaluate the test characteristics of transvaginal Saline Sonosalpingography (SSG) for the assessment of tubal patency to compare accuracy, positive predictive value and efficacy of sonosalpingogram with that of diagnostic laparoscopy in assessment of tubal patency. Assessing whether the fallopian tube is patent is part of initial evaluation in the procedure of seeking the cause of infertility. The incidence of the female infertility is 37%. The tubal factors account for 30% - 40%.

MATERIALS AND METHODS

A retrospective study was conducted at SVMCH, Ariyur, Pondicherry, in Department of Obstetrics and Gynaecology between June 2015 and March 2017. Tubal patency of 45 infertile women with previous unknown tubal function was assessed by transvaginal saline SSG at infertility clinic, SVMCH, Ariyur, Pondicherry. Main outcome measures were the prevalence, sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV), accuracy, false positive rate and false negative rate.

RESULTS

The results from transvaginal saline SSG were compared to the findings from the standard diagnostic laparoscopy with chromopertubation. Transvaginal saline SSG could detect tubal patency (Either unilateral or bilateral) with sensitivity, specificity, PPV, NPV and accuracy of 85.71%, 83.33%, 92.31%, 71.43% and 85% respectively.

CONCLUSION

The results confirm that transvaginal saline SSG is a simple, well-tolerated and reliable screening method for the assessment of tubal patency in an outpatient setting with minimal adverse effect. However, other confirmatory tests are required whenever bilateral tubal occlusion is suspected due to possible false negative finding.

KEYWORDS

Tubal Patency, Laparoscopy, Sonosalpingography, Infertility.

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BACKGROUND

Assessing whether the fallopian tube is patent is part of initial evaluation in the procedure of seeking the cause of infertility. The incidence of the female infertility is 37%. The tubal factors account for 30% - 40%.[1] The currently available procedures in the assessment of tubal patency, each with its drawbacks include Rubin test, which is highly subjective; laparoscopy, which is invasive and Hysterosalpingography (HSG), which exposes the patient to ionising radiation and contrast medium. Of the three techniques hysterosalpingography has been commonly used.[2] In recent years, major technologic advances in diagnostic ultrasound have led to improved image quality, particularly with the use of vaginal probes. Negative contrast like saline can be used to visualise the endometrial cavity. Spillage of fluid through fimbrial end in ultrasound colour Doppler, presence of fluid in periovarian region and Pouch of Douglas indicates the patency of the tube. Furthermore, it has been suggested as the first line method to evaluate tubal patency due to its benefits of simplicity and reliability compared to HSG and diagnostic laparoscopy.[3] Since early years of 80's, Sonosalpingography (SSG) have been introduced as the screening test for tubal patency.[2] Lately, it has been suggested as the first line method to evaluate tubal patency due to its benefits of simplicity and reliability compared to laparoscopy with chromopertubation as the "gold standard."[4,5] Laparoscopy is considered as gold standard for diagnosing tubal and peritoneal diseases. It allows visualisation of all pelvic organ and permits detection and potential concurrent treatment of intramural and subserosal uterine fibroids, peritubal and periovarian adhesion and endometriosis. Direct visualisation on laparoscopy using chromopertubation involves the transcervical instillation of methylene blue to directly visualise tubal patency and fimbrial architecture. With the invention of transvaginal transducer of high frequency, the genital organs can be better visualised. It also allows evaluation of tubal patency.

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The Sonosalpingography has also certain other advantages-

1. It is an outpatient procedure, less time consuming and cost effective.
2. It is a non-invasive procedure.
3. No anaesthesia is required.
4. It helps in the diagnosis of both uterine anomalies and pelvic pathologies.
5. It carries no radiation hazard.
6. It is reproducible and reliable for assessment of tubal patency.
7. It avoids allergic reactions seen in HSG-8. Tubal patency can be shown to the patients in real time.

Its Disadvantages and Limitations are–

1. Tubal spasm may lead to the diagnosis of tubal occlusion.
2. In hydrosalpinx, tubal flow may give a false impression of tubal patency.
3. It requires a degree of technical competence.
4. Site of the blockage cannot be detected precisely.
5. Intratubal pathology cannot be detected.
6. Peritubal adhesions and motility of the tubes cannot be assessed properly.
7. The findings are subjective.

Thus, SSG offers a much less invasive method of diagnosing tubal pathology, while maintaining a high sensitivity and specificity similar to that of laparoscopic chromopertubation. Moreover, SSG can be done for patients who have bronchial asthma or cardiac problems and are temporarily unfit for surgery. SSG can be offered initially to infertile patients. HSG or chromolaparoscopy can be deferred for 6 months after the start of treatment for infertility during which time other endocrinological and immunological factors can be worked up. If any discrepancy is found when assessing the tubal factors, then other tests can be done subsequently. If any abnormality is detected on SSG, HSG or laparoscopy can be done for confirmation.

Aims and Objectives

The aims and objectives of the study are to compare the diagnostic laparoscopy and sonosalpingography in evaluation of tubal patency in infertility and to compare accuracy, positive predictive value and efficacy of sonosalpingogram with that of diagnostic laparoscopy in assessment of tubal patency.

MATERIALS AND METHODS

Retrospective study conducted at Department of Obstetrics and Gynaecology, SVMCH, Ariyur, Pondicherry, during June 2015 and March 2017. Totally, there were 45 patients including primary and secondary infertility. SSG test done for all 45 cases. All the data were collected and analysed. Transvaginal saline SSG and diagnostic laparoscopy with chromopertubation for the assessment of tubal patency in infertile women were compared. Among 45 cases, 20 cases had undergone both SSG test and diagnostic laparoscopy in assessment of tubal patency and records were analysed. All women were in their proliferative phase of the menstrual cycle. Initially, transvaginal sonographic examination of the pelvis was performed in dorsal lithotomy position using high resolution vaginal probe. This was to assess normal free fluid in cul-de-sac as a baseline data. Under aseptic condition, number-8 paediatric Foley catheter was inserted and passed above the level of the internal os. The balloon was then inflated with 3 mL of isotonic saline solution and pulled down gently so the balloon fitted against the internal os. The transvaginal probe was reinserted followed by intermittent injection of 50 mL of sterile isotonic saline solution through the paediatric Foley catheter into the uterine cavity. Spillage of fluid through the fimbrial end noted in ultrasound colour Doppler. Then observed for the collection of fluid in the cul-de-sac for 2 minutes. The collection of fluid in the cul-de-sac or an increased volume of the pre-existing free fluid in cul-de-sac was considered as the evidence of at least unilateral tubal patency (positive test). Bilateral tubal occlusion was diagnosed by the absence of fluid collection in the cul-de-sac or static level of fluid in the cul-de-sac after the procedure (Negative test). In colour Doppler, absence or presence of spillage from fimbrial end revealed the block or patency of the tubes. After this procedure, the patient would be observed at rest for 30 minutes.

Analgesic drug was given if pelvic or shoulder pain was complained. Diagnostic laparoscopy with chromopertubation (Gold standard) was performed under general anaesthesia to evaluate pelvic pathology and tubal patency. This was performed by methylene blue dye injection. If the methylene blue dye could pass through the distal end of fimbria at least one side, it represented tubal patency (Positive test). Whereas the dye could not pass through the distal end of both fimbriae, it represented tubal occlusion (Negative test). Then, the results of transvaginal saline SSG were evaluated for its test characteristics in comparison to the laparoscopy with chromopertubation. The prevalence, accuracy, sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV), false-positive rate and false-negative rate were determined. Except mild pain during Foley's catheter insertion, no complications encountered.

RESULTS

Age (Years)	No. of Patient	Primary Infertility	Secondary Infertility	Total %
20 – 25	6	3 (30%)	3 (30%)	30%
26 – 30	5	2 (20%)	3 (30%)	25%
31 – 35	4	1 (10%)	3 (30%)	20%
> 35	5	4 (40%)	1 (10%)	25%

Table 1. Profile of the Patients (n= 20)

	Both Tubes Patent	Bilateral Tubal Blockage	Right Tube Patent	Left Tube Patent
Sonosalpingography	7 (35%)	7 (40%)	4 (15%)	2 (10%)
Laparoscopic with chromotubation	8 (40%)	6 (25%)	4 (20%)	2 (15%)

Table 2. Assessment and Correlation amongst the Two Tests for Tubal Patency

	Both Tubes Patent	Both Blocked	Total	Chi square Df = 1	P - value
Laparoscopic Chromopertubation (n= 20)	14	6	20	8.802	0.003
Sonosalpingography (n= 20)	13	7	20		

Table 3. Comparison of Laparoscopic Chromopertubation and Sonosalpingography for Tubal Patency

Saline Sonosalpingography	Laparoscopic with Chromotubation		Total
	Unilateral or Bilateral Tubal Patency	Bilateral Tubal Occlusion	
Unilateral or bilateral tubal patency	12	1	13
Bilateral tubal occlusion	2	5	7
Total	**14**	**6**	**20**

Table 4. Accuracy of Transvaginal Saline Sonosalpingography in Diagnosis of Tubal Patency

Total Number of Patients	20
True positives	12
True negatives	5
False positives	1
False negatives	2
Sensitivity	85.71%
Specificity	83.33%
Positive predictive value	92.31%
Negative predictive value	71.43%
False positive rate	28.57%
False negative rate	14.29%
Likelihood ratio if test positive	5.14%
Likelihood ratio if test negative	0.17%
Accuracy	85%
Prevalence	70%

Table 5. Evaluation of the value of Saline Sonosalpingography

Table 1– Among 20 women, 10 cases were primary infertile and 10 cases were secondary infertile. The mean age of women was 29.95 ± 5.89 years (Range 21 - 39 years). The mean married life of women was 5.30 ± 3.99 years (Range 1 - 19 years). Table 1 shows that majority (30%) of the women with primary and secondary infertility belonged to the age group of 20 - 25 years. In Table 2 and 3, SSG show tubal patency (Either unilateral or bilateral) in 13 cases and bilateral tubal occlusion in 7 cases. Laparoscopic chromopertubation showed tubal patency in 14 cases and bilateral tubal occlusion in 6 cases. The difference between these findings was statistically significant (p= 0.003). Tubal block was found more often on sonosalpingography than on diagnostic laparoscopy. However, in patients on diagnostic laparoscopy (n= 7), block was confirmed only in five cases. This indicates high rates of false positives for non-patency in SSG compared to the gold-standard laparoscopic technique. Therefore, all blocked fallopian tubes suspected on sonosalpingography should be confirmed by further evaluation with Laparoscopy.

These were confirmed by laparoscopy with chromopertubation in 14 and 6 women as tubal patency and tubal occlusion respectively. The PPV was 92.31% (95% CI, 81.30 - 96.20). The NPV was 71.43% (95% CI, 63.50 - 88.70). There were one false positive and two false negative cases. The sensitivity of transvaginal saline SSG in diagnosing unilateral or bilateral tubal patency was 85.71% (95% CI, 75.60 - 93.50) and the specificity was 83.33% (95% CI, 75.90 - 89.00). SSG could detect almost all cases of the tubal patency with high percentage of accuracy, 85%. It yielded sensitivity of 85.71% and specificity of 83.33%. When it predicted good tubal patency, only one case of tubal occlusion was diagnosed by laparoscopy with chromopertubation (False positive rate= 28.57, PPV= 92.31%, likelihood ratio if test positive= 5.14). However, when the SSG test showed 7 cases of tubal occlusion, two cases had tubal patency by laparoscopy with chromopertubation (False negative rate= 14.29, NPV= 71.43%, likelihood ratio if test negative= 0.17). From this information, it appears that transvaginal saline SSG is a good screening test of tubal patency. Nevertheless, when it shows tubal occlusion the test should be confirmed by other tests due to possible false negative finding.

DISCUSSION

In 2002, Suttipichate J et al[3] performed a prospective study to evaluate the characteristics of transvaginal saline Sonosalpingography (SSG) for the assessment of tubal patency in comparison to the findings from the standard diagnostic laparoscopy with chromopertubation. The results confirm that transvaginal saline SSG is a simple, well-tolerated and reliable screening method for the assessment of tubal patency in an outpatient setting with minimal adverse effect. In 2004, Seal Subrata Lall et al[6] conducted a study to find out whether sonosalpingography, which is a less invasive method can be used for assessment of tubal factor initially instead of the invasive methods like hysterosalpingography and diagnostic laparoscopy with chromopertubation. Results showed that as sonosalpingography has high sensitivity and specificity and is less invasive it should be used initially to assess tubal patency in cases of infertility. In 2006, Onah HE et al[7] described findings in 100 infertile Nigerian women who underwent sonosalpingogram in a prospective study. In 18 women the findings were confirmed with laparoscopy or laparotomy. Sonosalpingography was found to be a useful screening test for assessing endometrial, tubal and ovarian factors in infertile women, thereby obviating the need for laparoscopy and hysteroscopy in the majority of cases. Although, HSG and diagnostic laparoscopy with chromopertubation are useful for the assessment of tubal patency. Nevertheless, they have shown some unavoidable disadvantages. Compared to diagnostic laparoscopy which is the gold standard test for tubal study, although SSG is less accurate in evaluation of tubal patency and direct visualisation of pelvic pathology is not possible, but anaesthetic and surgical risk from the former procedure can be avoided especially when performed by an inexperienced hand. Moreover, transvaginal saline SSG may also be used to assess the tubal status after microsurgery for re-anastomosis in an outpatient setting. The results were compared to the findings at laparoscopy with chromopertubation performed

independently. One study showed 82% tubal patency with the SSG test.[1] Inki et al[5] in their report showed the sensitivity and the specificity were 90.20% and 83.30% respectively. Other studies[8] compared transvaginal SSG to laparoscopy with chromopertubation and found its accuracy in detection of tubal patency ranged from 76% - 87%. Sensitivity in detection of tubal occlusion was also high above 90%. Junjira et al[9] study showed that transvaginal saline SSG could detect almost all cases of the tubal patency with high percentage of accuracy, 95.24%. It yielded sensitivity of 96.97% and specificity of 88.89%. In our study when it predicted good tubal patency, only one case of tubal occlusion was diagnosed by laparoscopy with chromopertubation (False positive rate= 11.11, PPV= 96.97%, likelihood ratio if test positive= 8.73). However, when the test showed nine cases of tubal occlusion, one case had tubal patency by laparoscopy with chromopertubation (False negative rate= 3.03, NPV= 88.89%, likelihood ratio if test negative= 0.03). This study revealed one false positive case. This was probably due to interpretation error of ultrasonographic picture. False negative was detected in one case. This might be explained by the tubal spasm caused by injection of the media into the uterine cavity.[9] In our study, the sensitivity of transvaginal saline SSG in diagnosing unilateral or bilateral tubal patency was 85.71% (95% CI, 75.60 - 93.50) and the specificity was 83.33% (95% CI, 75.90 - 89.00). The laparoscopy show tubal patency (either unilateral or bilateral) in 14 women and bilateral tubal occlusion in 6 women. These were confirmed by SSG within 13 and 7 women as tubal patency and tubal occlusion respectively. It shows the positive predictive value was 92.31% (95% CI, 81.30 - 96.20). The negative predictive value was 71.43% (95% CI, 63.50 - 88.70). There were one false positive and two false negative findings. The sensitivity of transvaginal saline SSG in diagnosing unilateral or bilateral tubal patency was 85.71% (95% CI, 75.60 - 93.50) and the specificity was 83.33% (95% CI, 75.90 - 89.00). The results were compared to the findings at laparoscopy with chromopertubation performed independently. In their report, the sensitivity and the specificity were 90.20% and 83.30% respectively. There was broad agreement between the tubal findings from transvaginal saline SSG and laparoscopy with chromopertubation. Transvaginal saline SSG could detect almost all cases of the tubal patency with high percentage of accuracy, 85%. It yielded sensitivity of 85.71% and specificity of 83.33%. When it predicted good tubal patency, only one case of tubal occlusion was diagnosed by SSG (False positive rate= 28.57, PPV= 92.31%, likelihood ratio if test positive= 5.14). However, when the test showed six cases of tubal occlusion, 14 cases had tubal patency by laparoscopy with chromopertubation (false negative rate= 14.29, NPV= 71.43%, likelihood ratio if test negative= 0.17).

SSG could detect almost all cases of the tubal patency with high percentage of accuracy, 85%. The PPV was 92.31% (95% CI, 81.30 - 96.20). The NPV was 71.43% (95% CI, 63.50 - 88.70). From this information, it appears that transvaginal saline SSG is a good screening test of tubal patency, simple and convenient technique that possesses some beneficial aspects over HSG and laparoscopy with chromopertubation. It can be used as an alternative method to assess tubal patency in order to avoid many potential disadvantages of the conventional methods. However, repeated procedures or other confirmatory tests is still suggested if tubal occlusion is suspected due to possibility of false negative. Regarding to the adverse effects, other studies did not report any serious side effects. Except mild abdominal pain in two cases during insertion of Foley's catheter, no serious side effects in our study.

CONCLUSION

Transvaginal saline SSG is a simple and convenient technique that possesses some beneficial aspects over laparoscopy with chromopertubation. It can be used as an alternative method to assess tubal patency in order to avoid many potential disadvantages of the conventional methods. However, repeated procedures or other confirmatory tests is still suggested if tubal occlusion is suspected due to possibility of false negative.

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